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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,308	01/02/2002	Hugo A.G. Geerts	JAB-1515	8790

7590 11/19/2003

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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,308	GEERTS ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 49-51* is/are pending in the application.

4a) Of the above claim(s) *43 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42 and 49-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11 and 20-23, drawn to a nucleic acid vector comprising a nucleic acid sequence encoding human Tau, a sequence capable of directing expression in the nervous system, and a targeting sequences which facilitates integration of said vector into the genome of said animal so as to prevent expression of equivalent Tau protein and a cell comprising said vector.

Group II, claim(s) 12-19 and 20-23, drawn to a nucleic acid vector comprising a nucleic acid sequence encoding a human protein capable of modulating human Tau protein, a sequence capable of directing expression in the nervous system, and a targeting sequences which facilitates integration of said vector into the genome of said animal so as to prevent expression of am equivalent Tau-modulating protein and a cell comprising said vector.

Group III, claim(s) 24, and 39 drawn to a method of making a transgenic non-human animal comprising a single transgene encoding human Tau protein wherein said transgene disrupts the endogenous encoding a Tau protein equivalent wherein the method involves introducing said transgene into a cell of an embryo and the non-human animal.

Group IV, claim(s) 24,25, and 39, drawn to a method of making a transgenic non-human animal comprising a single transgene encoding human Tau protein wherein said transgene disrupts the endogenous encoding a Tau protein equivalent, the non-human animal.

Group V, claim(s) 26-28 and 40-42, drawn to a method of making a doubly transgenic non-human animal comprising introducing both a transgene encoding human Tau into the equivalent Tau gene of the animal and a transgene encoding a human protein capable of modulating human Tau protein into the equivalent Tau-modulating gene of the animal into an ES cell and generating an animal from the ES cell, and the non-human animal generated by said method.

Group VI, claim(s) 29,35-37,40-42 and 49-51, drawn to a method of making a doubly transgenic non-human animal comprising introducing a transgene encoding human Tau into the equivalent Tau gene of a first non-human animal, introducing a second transgene encoding a human protein

capable of modulating human Tau protein into the equivalent Tau-modulating gene of a second animal, and mating the animals to generate the doubly transgenic non-human animal.

Group VII, claim(s) 30-34 and 38, drawn to a method of making a transgenic non-human animal comprising a single transgene encoding human Tau wherein the human Tau transgene is integrated at a site other than the endogenous human Tau equivalent gene, and further comprising a second transgene that upon integration into the genome is capable of preventing expression of the endogenous Tau protein, wherein the method involves introducing said nucleic acids into a cell of an embryo.

Claim 43 is not considered in the instant Restriction as it is an improper dependent claim. Claim 43 is a method of using a double transgenic animal wherein the animal comprises a transgene encoding human Tau and a human Tau-modulatory protein. Claim 39 depends from claim 24, and requires using the animal made by claim 24. The animal made by claim 24, however, does not comprise a transgene encoding a human Tau-modulatory protein (kinase) which is required by claim 43. If applicant amends the claim, the claim will be examined with the appropriate Group. Claim 44 depends from claim 43 and is also not considered.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different categories of inventions will only be found to exist if the specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. Groups I-VI represent different products with distinct material compositions and uses. Groups III-VII represent different methods requiring different starting products and different method steps to practice the method. Group I is drawn to a nucleic acid and cells comprising the nucleic wherein the nucleic acid encodes a human Tau protein. The product of Group I can be used to overexpress and isolate human Tau protein. Group II is drawn to a nucleic acid and cells comprising the nucleic wherein the nucleic acid encodes a human Tau modulatory protein. The product of Group II can be used to overexpress and isolate human Tau-modulatory protein.

Groups III-VII are drawn to methods of making transgenic animals and the animals which can be used as disease models and do not require the nucleic acids of Groups I and II. The methods of making the animals of Groups III-VII are different and the animal made by each method differs one from the other. Groups III and VII are drawn to gene therapy methods wherein transgenes are introduced into cells of an embryo. Group IV is drawn to a method of making a transgenic animal by introducing a transgene encoding human Tau into the the endogenous Tau gene in a cultured ES cell and using said cell to generate a transgenic animal. Groups V and VI are drawn to methods of generating doubly transgenic non-human animals comprising transgenes encoding both human Tau and a human Tau modulating protein.

Group III is drawn to site-directed integration of the human Tau gene into the equivalent endogenous locus wherein Group VII involves random integration of a human Tau transgene and integration of a second transgene that disrupts the endogenous Tau gene.

Group V uses methods of introducing each transgene into an ES cell while Group VI involves methods of generating single transgenic animals followed by mating to generate a doubly transgenic animal.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Examiner
Art Unit 1632

MICHAEL WILSON
PRIMARY EXAMINER